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Proposed Maximum Residue Limit PMRL2013-104

Metalaxyl

(publié aussi en français)

14 November 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2013-104E (print version)
H113-24/2013-104E-PDF (PDF version)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the change in application rate for rapeseed (canola) on the product label of Apron XL LS Fungicide, containing technical grade metalaxyl-M and S-isomer, is acceptable. The specific uses approved in Canada are detailed on the label of Apron XL LS Fungicide, *Pest Control Products Act* Registration Number 25585.

The evaluation of this metalaxyl-M application indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Residues of the resolved isomer metalaxyl-M are covered by MRLs established for metalaxyl, the unresolved isomeric mixture. Consultation on the proposed MRLs for metalaxyl is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace MRLs already established for metalaxyl, are as follows.

Table 1 Proposed Maximum Residue Limits for Metalaxyl

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Metalaxyl	*N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-DL-alanine methyl ester, including metabolites that can be converted to the 2,6-dimethylaniline moiety, each expressed as metalaxyl equivalents.	0.05	Rapeseed (canola) (Crop Subgroup 20A) [a]

ppm = parts per million

[a] The MRLs are proposed to replace the currently established MRLs of 0.1 ppm.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

Currently, there are no American tolerances listed in the Electronic Code of Federal Regulations, and no Codex MRLs[1] listed on the Codex Alimentarius Pesticide Residues in Food website for metalaxyl in/on rapeseed (canola) (Crop Subgroup 20A) commodities.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for metalaxyl up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Previously reviewed residue data from field trials conducted with metalaxyl/metalaxyl-M in/on canola were reassessed in the framework of this petition. In addition, processing studies in treated canola were also reassessed to determine the potential for concentration of residues of metalaxyl/metalaxyl-M into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for metalaxyl was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL(s) for rapeseed (canola).

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limit(s) (MRLs)

Commodity	Application Method/ Total Application Rate	PHI (days)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
Canola	Seed treatment / 7–10 g a.i./ha	NA	<0.05	<0.05	No concentration observed

PHI = preharvest interval; ppm = parts per million

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of metalaxyl including metabolites that can be converted to the 2,6-dimethylaniline moiety. Residues of metalaxyl in these crop commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.